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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,828	11/24/1999	ROLF SKOLD	2964-102P	4478

7590 12/10/2002

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EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
1743	18

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/381,828	Applicant(s) Skold
	Examiner Arlen Soderquist	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Oct 3, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 3, 2002 has been entered.
2. Applicant's request for a personal interview prior to the instant office action has been considered. Due to the change in the rejection below an interview was not deemed to be appropriate and the request is not granted. A request for an interview in response to this office action would be appropriate.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchini in view of Baxter and Cunha or Reno and Bader, Li, Rodriguez or Saxberg (last seven newly cited and applied). In the paper Franchini teaches an approach to the problem of the dependence of the dissociation constant of weak electrolytes on the temperature and on the solvent composition in the ethane-1,2-diol-2-methoxyethanol solvent system. This empirical approach to clarify the problem of the dependence of the dissociation constants of weak electrolytes on temperature and composition of mixed solvents systems (X) is applied to the dissociation constant of picric acid

in ethane-1,2-diol, in 2-methoxyethanol and in their binary mixtures. The data are those of previous work (recalculated by means of the more accurate Fuoss-Hsia equation) integrated by the experimental data relative to 3 new mixtures. Two equations of the dependence of K on T and of K on X, respectively, were suggested and good accordance between experimental and calculated values are shown. Starting from the 2 above-mentioned equations, general empirical equations for the surface $K(T,x)$ are proposed; the average difference between calculated and experimental K values is ~8%. A three-dimensional plot of the function $K = K(T,X)$, figure 3 is presented. In the procedure section of page 1698, Franchini teaches that the solutions of picric acid of different concentrations were made by successive dilution of stock solutions. Franchini does not teach automated control of the dilutions in a single container.

In the abstract Baxter evaluates a simplified generalized standard additions method for calibration in the direct analysis of solid samples by graphite furnace atomic spectrometric techniques. In combining the principles of experimental design and the simplified approach to the generalized standard additions method, a useful calibration strategy was obtained for the single-component analysis of solid samples. By varying both the solid sample mass and the amount of analyte added, the observed response is defined by these 2 variables and may be geometrically described as a surface in 3-dimensional space. The use of multiple regression techniques then allows the analyte concentration in the solid to be computed from the response plane. Simultaneous blank correction and quantification was also performed. The importance of a well designed experimental lay-out and the effects of random errors or noise on the accuracy of the procedure were investigated, and some analytical results are given in the paper. The approximation of the analyte concentration obtained is fairly insensitive to curvature in the calibration function, but tends to be biased high in the presence of intense noise. This latter is a major limitation given the inhomogeneity of most solid samples which leads to irreproducible or noisy results.

In the paper Cunha discusses automated gravimetric management of solutions with a high-performance microcomputer-controlled gravimetric buret. A versatile gravimetric buret and the necessary interface that allows it to be controlled by an IBM-PC microcomputer are

described. The buret employs an electronic balance that holds three 30 mL flasks. The flasks are used for delivering different titrants or standard solutions and are connected to the sensor through the bottom of the balance. The addition of the solution is controlled by poly(tetrafluoroethylene) electromechanical valves housed inside the unit. The flasks can be refilled automatically from larger reservoirs placed outside the case. Solution level sensors are used to realize automatic refill when necessary. The mass delivered from the flasks is read by the computer through an RS232C interface. The buret can, when driven by the appropriate software, perform potentiometric, biampereometric and spectrophotometric titrations, standard additions procedures and the preparation of standard solutions.

In the paper Renoe presents an automated computer-controlled solution handling system utilizing weights. An automated sample and reagent solution preparation system, which is generally applicable in the analytical laboratory, was designed and tested. The new system utilizes an electronic sensor to weigh accurately the nominal aliquots of sample and reagent solutions that are added to a disposable beaker. Each plastic beaker on a turntable is automatically positioned on the weight sensor. Reagent and sample solutions are added by gravity feed for selected time intervals to provide nominal amounts. Each reagent or sample is accurately weighed after addition, and the beaker is then automatically moved to a stirring station while another beaker is moved into position for weight measurements. The amounts of reagents added to the beaker can be incrementally adjusted as desired. The operational modes are specified by interaction through FORTRAN programming and FORTRAN callable subroutines, which control or accumulate data concerning the system turntable, weight sensor, solution delivery devices and mixer, and the computer peripherals. The analytical utility of the system is demonstrated by data obtained in automated preparation of working curves and standard-addition procedures.

In the paper Bader presents a systematic approach to standard addition methods in instrumental analysis. Standard addition procedures in instrumental analysis are described, and variations possible with linear and nonlinear instruments are listed. Variations for linear instruments include continuous variation of standard at constant total volume, of unknown at

constant total volume, of both unknown and standard at constant total volume, variable volume single addition of standard, and variable total volume with continuous variation of standard. An example of a nonlinear response and examples of radiochemical techniques are also presented. In the first paragraph Bader teaches that the standard additions methods overcome or eliminate problems due to the calibration being performed with different sample matrices and differences in instrumental response. Relative to the instant claims case 5 (page 704) is important in that a single sample has multiple additions of a standard solution of the analyte. This case teaches that this method is particularly applicable to polarographic methods by reducing disturbances to the system and reducing the time for analysis due to changing of samples. Case 6 shows how case 5 can be applied to non-linear experiments.

In the paper Li presents a computer approach to ion-selective electrode potentiometry by two standard additions and subtractions methods through ionic strength calibration. The effect of ionic strength in standard additions and subtractions methods has been utilized for determining an unknown concentration using an ion-selective electrode without prior calibration of the electrode. In the simplest instance, only 2 standard additions or subtractions are required. An initial value of unknown concentration or electrode slope is first assumed to solve the equations repeatedly. This method gives greater accuracy than the methods which are used at present. The method was used to evaluate the unknown concentration and electrode slope. The blank solution has the same ionic strength as the standard solution in the 2 standard additions method. In the 2 standard subtractions method, a suitable blank solution is chosen. The effectiveness of computer iterative solution of the 2 standard additions method is demonstrated on a lead sample.

In the paper Rodriguez discusses validation of an analytical instrumental method by standard addition. A statistical procedure to validate an analytical methodology by standard addition methodology is described. The data set obtained in 3 calibration experiments with standard dilutions, standard additions, and portions of sample was used. The accuracy of the analytical results is checked by comparison of analyte contents in the different calibrations and from the recovery. Mathematical expressions to estimate the statistical parameters are proposed. The statistical protocol was applied to fluorometric determination of Mo with alizarin S in

vegetable tissues. In the experimental section of page 472 Rodriguez discusses the procedures used for the standard calibration -- different analyte standard solutions and replicates of each solution-- and the standard addition calibration -- continuous variations of standard at constant volume. It is clear that the standard additions method does not require replicates.

In the paper Saxberg presents a generalized standard addition method. The normal standard addition method assumes that for any 1 analyte in a sample there is an analytical sensor which responds to that analyte and no other component in the sample. When the analytical sensor is not completely selective, so-called interference effects result which can be a major source of error. The generalized standard addition method (GSAM) provides a means of detecting interference effects, quantifying the magnitude of the interferences, and simultaneously determining analyte concentrations. The GSAM as presented in the paper uses multiple linear regression to analyze multicomponent samples where the response-analyte concentration relation is of some arbitrary polynomial form; for a nonlinear polynomial relation, an iterative solution is required. In the first paragraph of the paper, Saxberg teach that the standard addition method is well known to all analytical chemists along with its use to overcome sample and/or method associated interferences such as residual matrix effects. the second paragraph teaches that in the method a linear change in the response of the analyte is assumed. Thus plotting the response change for several successive additions of the analyte to a sample with an unknown analyte concentration allows the analyte concentration to be found.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the successive dilutions of Franchini with the successive additions of an analyte containing solution of known concentration according to the teachings of Bader, Li, Rodriguez or Saxberg because of the reductions of interferences due to matrix effects and the greater accuracy through use of a standard additions method as taught by Bader, Li, Rodriguez and Saxberg. Additionally one of skill in the art would have recognized that as taught by Baxter the standard additions method is capable of being performed with two independent variables and one dependent variable with the result being plotted as a three-dimensional graph. It would have been obvious to one of ordinary skill in the art at the time the invention was made to automate

the Franchini method through use of an automated liquid handling system as taught by Cunha or Renoe because of the flexibility and versatility of liquid handling as taught by Cunha and Renoe. Additionally the Courts have held that providing a mechanical or automatic means to replace manual activity which accomplishes the same result is within the skill of a routineer in the art (see *In re Venner*, 120 USPQ 192 (CCPA 1958)).

5. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art relates to automated liquid handling and methods involving standard additions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



December 4, 2002

ARLEN SODERQUIST
PRIMARY EXAMINER